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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,227	10/03/2003	Hiroaki Ito	053466-0365	8597

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
08/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,227	ITO ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,25,26,38,39 and 43-47* is/are pending in the application.

4a) Of the above claim(s) *1-13,25,26,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/4/07, 4/20/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Original claims 1-13, 25-26, 38-39 are withdrawn from consideration. Claims 14-24, 27-37, 40-42 have been canceled (8/2/07). New claims 43-47 are under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 8/2/2007 is acknowledged.

3. The following previous objections and rejections are withdrawn in light of applicants amendments filed on 8/2/2007:

(i) the rejection of claims 27-37 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter;

(ii) the rejection of claims 14-19, 22, 24, 27-37 and 40-42 under 35 U.S.C. 112, first paragraph, for lack of adequate written description;

(iii) the rejection of claims 14-19, 22, 24, 27-37, 40-42, under 35 U.S.C. 112, second paragraph;

(iv) the provisional rejection of claims 14-19, 22, 24, 27-37 and 40-42 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,723,319 ('319).

4. Applicant's arguments filed on 8/2/2007 have been fully considered and were persuasive in part. The issues remaining are restated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite "a method of treating inflammatory bowel disease by administering an antibody to the IL-6 receptor".

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action (12/5/2006).

Claim rejections-35 USC § 112, scope of enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. Claims 43-47, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammatory bowel disease by administering effective amount of monoclonal antibody, PM-1 or MR16-1 against the human IL-6 receptor, does not reasonably provide enablement for a method of preventing or treating inflammatory bowel disease by administering "all" anti-interleukin-6 receptor antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 3-7 of the previous Office action (12/5/2006).

Since Applicants have failed to submit arguments demonstrating the error in this rejection by the Examiner, this rejection is maintained for reasons of record.

Claim rejections-35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8a. Claims 43-44, 47, are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/38481.

This rejection is maintained for reasons of record set forth at pages 12-13 of the previous Office action (12/5/2006).

Applicants argue that the '481 reference teaches that blocking of all gp 130-related signals is useful for treatment of inflammatory diseases and that the present invention treats inflammatory bowel diseases through blocking only the IL-6 related signal. However, contrary to Applicants arguments, claim 43 recites "comprising" which is open language. Therefore, the method of treating inflammatory diseases as encompassed by the instant claims, is not specific to blocking a signal only through the IL-6 receptor but also encompasses blocking a signal via the other receptors i.e. leukemia inhibitory factor, ciliary neurotrophic factor, oncostatin M and cardiotrophin-1 receptors. Therefore, from the instant claims one of ordinary skill in the art would conclude that the instant antibody to the IL-6 receptor not only blocks IL-6 signal transduction but possibly the signal transduction via the leukemia inhibitory factor, ciliary neurotrophic factor, oncostatin M and cardiotrophin-1 receptors. Therefore, the reference anticipates instant claims 43-44, 47.

Applicants arguments with respect to the Harrison et al (1996) reference are non-persuasive because the claims as recited encompass the method This rejection can only be obviated by reciting a method of treating inflammatory disease comprising administering the specific PM-1 or MR16-1 antibodies to the IL-6 receptor.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9a. Claims 43-47 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 96/38481 in view of Queen et al. (U.S. Pat No. 5,530,101).

This rejection is maintained for reasons of record set forth at pages 13-14 of the previous Office action (12/5/2006).

Applicants argue that the Queen reference teaches the production of antibody fragments, including the FAB fragment and the production of chimeric antibodies and the humanization of monoclonal antibodies as well as designing a humanized antibody that retains affinity for its antigen and that nothing in this reference suggests using an antibody fragment of an anti-interleukin-6 receptor to treat inflammatory bowel disease. Applicants also argue that the '481 reference does not teach, suggest or motivate one of ordinary skill in the art to treat inflammatory bowel disease through blocking the IL-6 receptor alone and accordingly applicants request the examiner withdraw this rejection and allow the new claims 43-47. However, as argued by the Examiner in paragraph 8 above, since claim 43 recites the term "comprising", this language encompasses treating inflammatory bowel diseases by blocking a signal via the other receptors i.e. leukemia inhibitory factor, ciliary neurotrophic factor, oncostatin M and cardiotrophin-1 receptors. Therefore, reference '481 in view of Queen '101 renders obvious claims 43-47.

Conclusion

No claim is allowable.

Claims 43-47 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
August 9, 2007